

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Michael Austin, Don Robinson, Dennis R. Boulais, Praveen Kulkarni, Toby Freyman, Samuel J. Epstein, Wendy Naimark, Marlene Schwarz
Application No.:	10/797704
Filed:	March 9, 2004
For:	Coated Medical Device and Method for Manufacturing the Same
Examiner:	Laura Estelle Edwards
Group Art Unit:	3738

Mail Stop Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Docket No.: S63.2B-14067-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified Application in which claims 17, 19-29 and 36-39 were rejected in the Final Office Action mailed November 30, 2009. A Notice of Appeal was filed in this case on March 1, 2010. This brief is submitted in accordance with 37 CFR. § 41.37. The fees required under 37 CFR § 41.20(b)(2), and any petition for an extension of time required for filing this brief, are addressed in the accompanying Transmittal Letter.

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(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related appeals or interferences are pending.

(iii) Status of Claims

Claims 17, 19-29 and 36-39 are pending in the application. Claims 1-16, 18 and 30-35 were previously canceled. Claims 17, 19-29 and 36-39 have been finally rejected and are the subject of this appeal.

(iv) Status of Amendments

A Response After Final was filed on February 1, 2010, which presented arguments but did not amend the claims. No claim amendments have been filed subsequent to the Final Office Action.

(v) Summary of Claimed Subject Matter

Independent claim 22 recites a system for coating a stent having a tubular portion with an outer surface. A coating material source 94 contains a coating material 95 comprising a solvent and a biologically active material. See Figure 9A, provided below, and paragraphs 0045 and 0068. A first roller 91 has a surface 96 and a second roller 92 has a surface 97. A doctor blade 93 in proximity to the first roller surface 96 is positioned to remove excess coating material from the first roller surface 96. See paragraph 0068. The first roller 91 is situated relative to the coating material source 94 so that the coating material 95 in the coating material source 94 is transferred to the first roller surface 96. See paragraph 0068. The first roller 91 and second roller 92 are situated relative to each other so that the first roller 91 transfers the coating material 95 transferred to the first roller surface 96 to the second roller surface 97. See paragraph 0068. The second roller 92 is situated relative to the tubular portion 90 so that the second roller 92 transfers the coating material 95 transferred to the second roller surface 97 to the outer surface of the tubular portion 90. See paragraph 0068.

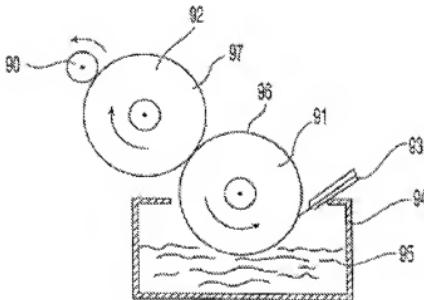


Fig. 9A

Claim 17 depends from claim 22 and recites a reservoir that continuously supplies the coating material source with coating material. See paragraph 0011.

Claim 19 depends from claim 17 and requires the reservoir to be a fermentor containing cells. See paragraph 0061.

Claim 20 depends from claim 17 and requires the coating material to be circulated between the reservoir and the coating material source. See paragraph 0061.

Claim 21 depends from claim 22 and requires the surface of the second roller to comprise a plurality of grooves. See paragraph 0077.

Claim 23 depends from claim 22 and requires the surface of the second roller to be rougher than the surface of the first roller. See paragraph 0070.

Claim 39 depends from claim 22 and requires a distance between the first roller and the second roller to be adjustable to control the thickness of the coating material. See paragraph 0067.

(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Whether US 6111345 is a translation of JP 11-111423.

Issue 2: Whether the Examiner erred in rejecting claims 21-26 and 36-38 under 35 USC § 103 over Pacetti (US 2005/0074544) in view of Shibata (JP 11-111423), and in rejecting claims 27-29 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Kirk Othmer (Encyclopedia of Chemical Technology).

Issue 3: Whether the Examiner erred in rejecting claims 17 and 20 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Pacetti '874 (US 7175874).

Issue 4: Whether the Examiner erred in rejecting claim 19 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Layrolle (US 2001/0008649).

Issue 5: Whether the Examiner erred in rejecting claim 39 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Pomper (US 2842092).

(vii) Argument

Issue 1: Whether US 6111345 is a translation of JP 11-111423.

All of the rejections rely upon a primary combination of Pacetti in view of Shibata (JP 11-111423). Shibata is a non-English reference. The Examiner has provided an English abstract of Shibata, and also alleged that US 6111345 is equivalent to Shibata. If US 6111345 is not a translation of Shibata, then the rejections can only rely on teachings from the English abstract.

Shibata is a foreign, non-English reference with no direct English equivalent. Applicants' request for an English translation was acknowledged in the Final Office Action mailed November 30, 2009, although a translation was not provided at that time – thus, the rejection was made final before Applicants were provided with a translation of the applied reference. On March 2, 2010, subsequent to expiration of the 3-month period for response to the Final Office Action, the Examiner provided US 6111345 as an alleged English equivalent to Shibata.

US 6111345 is not a true English translation of Shibata because it clearly includes subject matter that goes beyond the scope of Shibata. For example, the '345 patent cover page indicates that it is related by priority to seven Japanese patent documents, none of which are the Shibata reference (JP 11-111423; application no. 10-30049) relied upon in the rejection. At most, Shibata claims priority to a Japanese application (no. 9-211950) that US 6111345 also claims priority to. The Shibata reference applied in the rejection was filed February 12, 1998, which is after the August 28, 1997 filing date of the US reference that is asserted to be equivalent. Therefore, it is unclear how US 6111345 can be an actual translation of JP 11-111423.

It is also unclear whether the original Shibata reference includes teachings that are not included in US 6111345. Therefore, US 6111345 cannot be relied upon as a translation of Shibata for the purposes of supporting a rejection that applies Shibata.

The Examiner is only entitled to rely upon teachings from the English abstract of Shibata, and not teachings from the underlying Shibata JP reference, because a translation of the underlying Shibata JP reference has not been provided. See MPEP 706.02(II).

Applicants request that the Board find that US 6111345 is not a direct translation of Shibata, and that only teachings from the English abstract of Shibata are available for purposes of the current rejections, which apply Shibata but do not apply US 6111345.

Issue 2: Whether the Examiner erred in rejecting claims 21-26 and 36-38 under 35 USC § 103 over Pacetti (US 2005/0074544) in view of Shibata (JP 11-111423), and in rejecting claims 27-29 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Kirk Othmer (Encyclopedia of Chemical Technology).

The Examiner erred in rejecting claims over Pacetti in view of Shibata because a *prima facie* case of obviousness has not been presented. The Shibata reference is non-analogous art that should not be used in rejecting the pending claims. Even if Shibata is found to be analogous, the Examiner has used impermissible hindsight and unsupported conclusory arguments to broaden the teachings of Shibata and to propose the modification(s) at issue. Further, the rejection relies upon teachings that go beyond the scope of the English abstract of Shibata.

The rejection over Pacetti in view of Shibata and further in view of Kirk Othmer is traversed based upon the primary combination of Pacetti and Shibata. Thus, the rejection of claims 27-29 will stand or fall along with the rejection of claims 21-26 and 36-38.

Applicants have argued under Issue 1 that US 6111345 is not a translation of Shibata. The arguments presented under Issue 2 are divided into sections – the non-analogous art issue is discussed first, then arguments are presented against a combination of Pacetti and the Shibata English Abstract, and then arguments for if US 6111345 is available for consideration.

Non-Analogous Art

A reference can be analogous if, because of the matter with which the reference deals, the reference logically would have commanded itself to an inventor's attention in considering his or her invention as a whole. See *KSR v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

The pending claims are directed to a “system for coating a stent” that provides a “biologically active material” coating. A person of ordinary skill in the art would recognize that a stent is a delicate, sterile medical device that must be suitable for use inside the human body. Stents and stent coatings must be manufactured and handled with great care.

Conversely, Shibata is directed to spark plugs and applying conductive paste to spark plugs. The conductive paste is not biocompatible. Shibata does not disclose or suggest any

coatings that would be suitable for use on a stent. The "Problem to be Solved" by Shibata is "To provide a spark plug which can inhibit generation of a spike noise in a detected waveform of an ion current detecting device." See English Abstract.

In view of these differences, a person of ordinary skill in the claimed art of stent coating would not look to the spark plug/electrical spike teachings of Shibata for guidance. Therefore, Shibata is non-analogous prior art to the pending claims.

Applicants request that the Board find Shibata to be non-analogous art and reverse all of the rejections asserted by the Examiner.

Issue 2 Arguments if US 6111345 is Not a Translation of Shibata

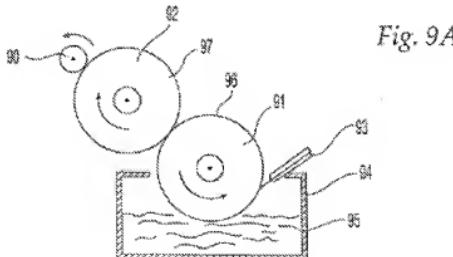
If US 6111345 is found to not be a translation of Shibata, then only teachings from the English abstract of Shibata are available for purposes of the current rejections.

Claim Limitations

An obviousness rejection requires a suggestion of all limitations in a claim. See *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Claim 22 recites "a doctor blade in proximity to the first roller surface positioned to remove excess coating material from the first roller surface."

Figure 9A of the application, provided below, illustrates a doctor blade 93 positioned as claimed.



The Examiner admits that Pacetti does not teach a doctor blade as claimed, and asserts that Shibata "provides for one or more metering mechanisms in the form of blades

(500/100) for removal of excess coating material.” See Final Office Action at page 2.

The English Abstract of Shibata does not support the statements asserted by the Examiner. The Abstract is recreated below.

PROBLEM TO BE SOLVED: To provide a spark plug which can inhibit generation of a spike noise in a detected waveform of an ion current detecting device

SOLUTION: In this method, film formation that forms conductive film on a stepped part 32a and extended part 32c of an insulator 32 provided with a peripheral part of the other end 322 side is carried out. Here, first, conductive paste 390 is applied to side circumference of a roller part 201 in the prescribed shape corresponding to the conductive film to be formed on the extended part 32c, thereafter the conductive paste 390 of the prescribed shape is transferred on the extended part 32c of the insulator 32, by rotating a roller part 301 under the condition that side circumference of the roller part 301 is contacted with the peripheral part of the insulator 32, then a part of the conductive paste 390 transferred on the extended part 32c is moved to the stepped part 32a by its own weight. Thereafter, the conductive paste 390 is baked.

The Abstract does not mention a “metering mechanism,” a “blade” or reference characters 500 or 100, as discussed by the Examiner.

Therefore, the combination of Pacetti and the Shibata Abstract does not disclose or suggest each limitation of independent claim 22, or of any claim dependent therefrom.

Combination/Modification

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

The Examiner asserts that Pacetti teaches many limitations of independent claim 22, but admits that Pacetti does not disclose or suggest a “second roller” oriented as required by claim 22. See Non-Final Office Action mailed May 12, 2009 at page 3.

The Examiner further alleges, “it was known...to provide for an indirect roller coating arrangement to enable a more metered coating of a cylindrically shaped object as evidenced by Shibata.” The Examiner then concludes:

Thus, it would have been obvious to one of ordinary skill in the art to utilize an indirect coating arrangement as taught by Shibata in place of the Pacetti direct coating arrangement as an alternative arrangement for coating the stent to allow for a more metered supply of coating material onto the surface of the stent thereby enhancing uniformity in coating on the surface of the stent.

The Examiner's assertions are traversed. Although Shibata discloses a coating system having two rollers (201 and 301 – see English Abstract), the Examiner has not cited to any teaching that supports the conclusion that the Shibata two-roller coating system "enable[s] a more metered coating" or "enhance[es] uniformity in coating" over the Pacetti coating system.

The rejection relies upon a theory that an indirect, two roller coating system is capable of providing a more metered/uniform coating than a single roller coating system. This theory appears to be the motivation for the proposed modification to Pacetti; however, the Examiner has not cited to a prior art teaching that supports such a broad general assertion comparing direct and indirect coating systems. Shibata teaches a specialized system for applying conductive paste to a spark plug; however, the Examiner characterizes Shibata as generally teaching an "indirect coating system" that represents an improvement over the Pacetti system. Thus, the Examiner has used impermissible hindsight in broadening Shibata's actual teachings of a specific type of two roller coating system designed for spark plugs (i.e. a species) into a general teaching of an indirect coating system (i.e. a genus). The Examiner has also concluded that the genus of indirect coating systems are better than single roller systems; however, this conclusion is not supported by Shibata.

It is not reasonable to assume that the Shibata method/system for coating spark plugs, published in 1999, would produce better stent coatings than the Pacetti method for coating stents published in 2005. The Examiner has provided reasoning that the Shibata system would allow for more instances of excess coating to be removed, allowing the coating to be smoother and more uniform. See e.g. Non-Final Office Action at page 3 and Final Office Action at page 5. Again, the Examiner has not cited to any prior art teaching that compares direct and indirect roll coating systems. As such, the Examiner's reasoning amounts to mere speculation.

The Examiner has not cited to any prior art teaching that would actually motivate a

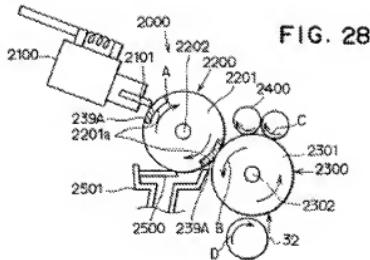
person of ordinary skill in the art to modify Pacetti's stent coating system to use multiple rollers from Shibata. The English Abstract does not support the conclusions reached by the Examiner regarding an "indirect coating system" being better than a direct coating system.

The motivation for the Examiner's proposed modification stems from the Examiner's conclusion that an "indirect coating system" would be better than the original Pacetti system. Since this conclusion is not supported by the applied references, the Examiner has not articulated a reason that would have motivated the proposed modification. Therefore, the Examiner has not presented a *prima facie* case of obviousness against any claim rejected over Pacetti in view of Shibata.

Issue 2 Arguments if US 6111345 Can be Considered

Even if the teachings of US 6111345 are available, the Examiner's rejection is not supported.

US 6111345 teaches the use of a marking roller 2200 and a transfer roller 2300. See Figure 28, provided below, and column 20, lines 40-45. The marking roller 2200 is provided with recesses 2201a that become filled with conductive paste 239A. See column 21, lines 23-26.



The transfer roller 2300 receives the conductive paste 239A from the recesses 2201a of the marking roller 2200, and transfers the paste 239A to the insulator/spark plug 32. See column 21, lines 31-34 and 49-53.

The recesses 2201a are shaped to form a conductive band of hatching and a product number. See e.g. column 20, lines 31-37 and Figures 27A-27C, provided below.

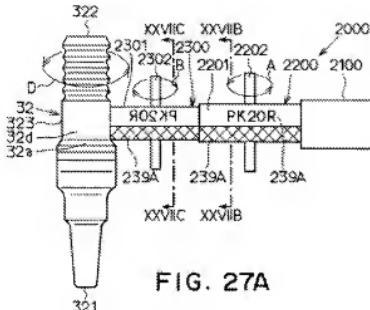


FIG. 27A

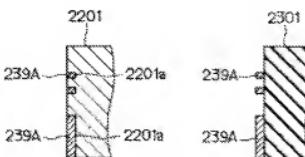


FIG. 27B

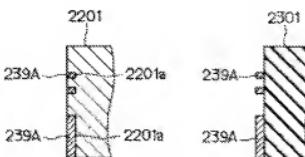


FIG. 27C

Figure 27A shows how the rollers 2200, 2300 are oriented with respect to one another. Figure 27B shows the conductive paste 239A situated within the recesses 2201a of the transfer roller. Figure 27C shows the conductive paste 239A on the surface of the transfer roller, after the paste 239A was removed from the recesses 2201a. See column 20, line 38-column 21, line 55.

Shibata teaches, "The marking roller 2200 is made of metallic material such as iron, copper, or the like," and "transfer roller 2300 is made of elastic material such as rubber." See column 20, lines 58-66. Shibata further states, "because the roller portion 2301 is made of elastic material, the circumferential surface of the roller portion 2301 adheres to the circumferential surface of the roller portion 2201 biting into the recesses 2201a, so that, as shown in FIG. 27C, the conductive paste 239A held in the recesses 2201a is transferred to the circumferential surface of the roller portion 2301." See column 21, lines 31-40.

Thus, Shibata teaches using a metal (e.g. rigid, inelastic) marking roller having recesses of a particular shape in conjunction with an elastic (e.g. deformable) transfer roller. The marking roller shapes the coating material, and the transfer roller removes the coating material from the recesses of the marking roller and transfers the coating to the product.

A person of ordinary skill in the art would not have been motivated to modify Pacetti as proposed by the Examiner. Shibata teaches a specialized coating system for spark plugs that uses a marking roller and a transfer roller. Each Shibata roller performs a specific function, and the functionality of the Shibata rollers is not necessary in the Pacetti device. Conversely, if Pacetti were modified to have a Shibata marking roller having shaped recesses, the resulting

coating would have coverage gaps. A person of ordinary skill in the art would recognize that a stent with coating coverage gaps would be less desirable than the original coated Pacetti stent. Thus, the modification proposed by the Examiner has a likelihood of being detrimental to Pacetti.

The Examiner has not discussed any reason for configuring Pacetti to have a marking roller and a transfer roller as taught by Shibata. The Examiner concludes that the “indirect coating system as taught by Shibata” would “allow for a more metered supply of coating material” (see e.g. Non-Final Office Action at page 3); however, this conclusion stems from an assumption that indirect coating arrangements are better than direct coating arrangements. The Examiner has not cited to any teaching that supports such a conclusion, and the Examiner’s conclusion cannot be reached from the disclosures of Pacetti and Shibata alone.

Instead, the Examiner has used impermissible hindsight to first broaden the teachings of Shibata beyond what is actually disclosed, then to propose a modification that only stems from the impermissibly broadened teachings. The Examiner has not articulated a reason why a person of ordinary skill in the art, viewing Pacetti and Shibata without the benefit of impermissible hindsight, would have been prompted to modify the Pacetti device in a way that would meet the limitations of the pending claims. Therefore, The Examiner has not provided a *prima facie* case of obviousness against the rejected claims.

Issue 2 Conclusion

In view of the foregoing remarks, Applicants assert that the Examiner has not presented a *prima facie* case of obviousness against independent claim 22, or any claim dependent therefrom. Applicants request that the Board reverse the rejection of claims 21-26 and 36-38 under 35 USC § 103 over Pacetti in view of Shibata, and reverse the rejection of claims 27-29 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Kirk Othmer.

Dependent Claim 21

Claim 21 recites, “wherein the surface of the second roller comprises a plurality of grooves.”

In the rejection, Shibata’s transfer roller 2300 is the roller that would satisfy the “second roller” limitation of claim 21; however, Shibata does not disclose or suggest that the

transfer roller 2300 includes grooves.

The Shibata English Abstract does not support the rejection, and even if the teachings of US 6111345 are available for consideration, US 6111345 does not disclose or suggest a “second roller” that includes “a plurality of grooves” as recited in claim 21.

Therefore, the applied references do not disclose or suggest each limitation of claim 21, and Applicants request that the Board reverse the rejection of claim 21 under 35 USC § 103 over Pacetti in view of Shibata.

Dependent Claim 23

Claim 23 recites, “wherein the surface of the second roller is rougher than the surface of the first roller.”

In the rejection, Shibata’s transfer roller 2300 is the roller that would satisfy the “second roller” limitation of claim 23 and Shibata’s marking roller 2200 is the roller that would satisfy the “first roller” limitation of claim 23; however, Shibata does not disclose or suggest that the transfer roller 2300 is rougher than the marking roller 2200.

The Shibata English Abstract does not support the rejection, and even if the teachings of US 6111345 are available for consideration, US 6111345 does not disclose or suggest a “second roller” having a surface that “is rougher than the surface of the first roller,” as recited in claim 23.

Therefore, the applied references do not disclose or suggest each limitation of claim 23, and Applicants request that the Board reverse the rejection of claim 23 under 35 USC § 103 over Pacetti in view of Shibata.

Issue 3: Whether the Examiner erred in rejecting claims 17 and 20 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Pacetti ‘874 (US 7175874).

The rejections discussed under Issue 3 rely upon reasoning from the primary combination of Pacetti and Shibata, which is discussed under Issue 2. If the rejections over Pacetti and Shibata are reversed, the rejections discussed under Issue 3 should be reversed for at least the reasons discussed with respect to Issue 2.

Further, a person of ordinary skill in the art would not have been motivated to

combine portions of the Pacetti '874 device as proposed by the Examiner.

At page 5 of the Non-Final Office Action, the Examiner asserts:

It would have been obvious to one of ordinary skill in the art to provide the stent coating material supply arrangement as taught by Pacetti '874 in indirect arrangement as defined by the combination above in order to allow for control of the concentration of ingredients used to form the final composition for application to the stent.

Thus, the Examiner proposes to use the Pacetti '874 "coating material supply arrangement" with the modified Pacetti/Shibata indirect roller coating system proposed by the Examiner under Issue 2.

The Pacetti roller coating system and the Pacetti '874 spray coating system work under different theories of operation. As such, the two systems are not readily combinable with one another as proposed by the Examiner.

The Examiner does not specifically discuss how the Pacetti roller coating device would be modified to use the Pacetti '874 "coating material supply arrangement."

The Pacetti roller coating device operates at normal atmospheric pressure and relies upon gravity when the coating material is supplied. See e.g. Pacetti Figures 10 and 12, provided below.

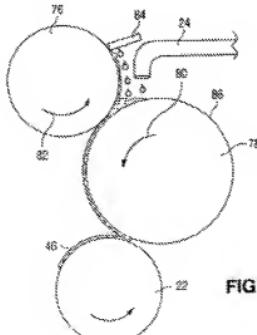


FIG. 10

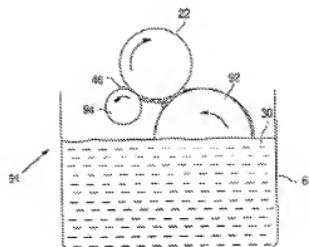
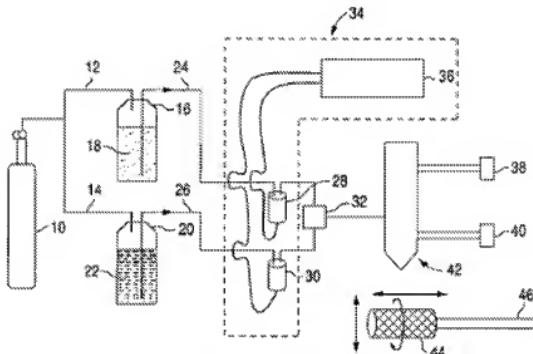


FIG. 12

Pacetti '874 teaches a spray coating system that sprays the coating material at high pressure. The system has two reservoirs 16, 20, each having a different coating solution. An air compressor 10 delivers pressurized air to the reservoirs 16, 20, and the coatings are forced through a mixer 32 and then sprayed through a nozzle 42 at the stent 44. See Figure 1, provided below, and column 3, lines 26-54.



Pacetti '874 FIG. 1

A person of ordinary skill in the art would not have been motivated to combine portions of the high pressure spray coating device with the roll coating device as proposed by the Examiner. The rejection has not articulated which components from Pacetti '874 pressurized system would be used, or how those components from the pressurized system would specifically be incorporated into the atmospheric pressure Pacetti roller coating device. Therefore, a *prima facie* case of obviousness has not been presented.

Applicants request that the Board reverse the rejection of claims 17 and 20 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Pacetti '874.

Dependent Claim 20

Claim 20 recites, "wherein the coating material is circulated between the reservoir and the coating material source."

The Examiner asserts that Pacetti '874 teaches the "circulated" limitation recited in claim 20. See Non-Final Office Action at page 5. This assertion is traversed.

Pacetti '874 does not teach circulation as required by claim 20. Pacetti '874 teaches one-way flow of the coating material (e.g. from reservoir 18 to mixer 32), but does not teach a system wherein "coating material is circulated between the reservoir and the coating material source."

Claim 20 requires more than mere one-way flow between the reservoir and the coating material source. Claim 17 recites "a reservoir that continuously supplies the coating material source with coating material." Thus, the system of claim 17 requires flow (e.g. at least one-way flow) from the reservoir to the coating material source. Claim 20 depends from claim 17 and further recites the circulation between the reservoir and the coating material source.

Under the doctrine of claim differentiation, there is a presumption that claims 17 and 20 have a different scope. Since claim 17 inherently requires flow (e.g. at least one-way flow), the circulation recited in claim 20 must be directed to more than mere one-way flow. Thus, the circulation recited in claim 20 requires flow from the coating material source back to the reservoir.

Applicants submit a dictionary definition of the term "circulate" that supports the requested claim construction. See "circulate." The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. 21 May. 2010. <Dictionary.com <http://dictionary.reference.com/browse/circulate>>.

cir·cu·late (sür'kyü-lät') ⓘ
v.
v. cir·cu·lat·ed, cir·cu·lat·ing, cir·cu·lates
v. intr.
1. To move in or flow through a circle or circuit: *blood circulating through the body*.

The dictionary definition suggests a closed loop, reciting a "circle or circuit," which would allow the two-way flow discussed above. This is consistent with Applicants' asserted definition.

Pacetti '874 does not disclose or suggest circulation. Thus, the applied references do not disclose or suggest each limitation of claim 20, and even if the modifications proposed by the Examiner were made, the resulting device would not meet the limitations of claim 20. Therefore, a *prima facie* case of obviousness has not been presented.

Applicants request that the Board reverse the rejection of claim 20 under 35 USC

§ 103 over Pacetti in view of Shibata and further in view of Pacetti '874.

Issue 4: Whether the Examiner erred in rejecting claim 19 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Layrolle (US 2001/0008649).

The rejections discussed under Issue 4 rely upon reasoning from the primary combination of Pacetti and Shibata, which is discussed under Issue 2. If the rejections over Pacetti and Shibata are reversed, the rejections discussed under Issue 4 should be reversed for at least the reasons discussed with respect to Issue 2.

Further, the Examiner erred in rejecting claim 19 because a person of ordinary skill in the art would not have been motivated to combine the reservoir of Layrolle with the roller coating system of Pacetti.

The Examiner asserts that Layrolle teaches the use of a “source/reservoir to be in the form of a fermentor system,” and that it would have been obvious to include “at least one source having appropriate materials to effect a fermentor...in the indirect [coating] arrangement” proposed by the Examiner in view of Pacetti and Shibata. See Non-Final Office Action at page 6.

Based upon the teachings of Layrolle, a person of ordinary skill in the art would not have attempted to coat a stent with the coating materials/source taught by Layrolle in conjunction with a roller coating device because there would not be a reasonable expectation of success.

Layrolle teaches a specialized coating system where the implants/stents are immersed and soaked in a calcifying solution, wherein the coating is grown on the implants/stents. See e.g. Abstract and Figure 1, provided below.

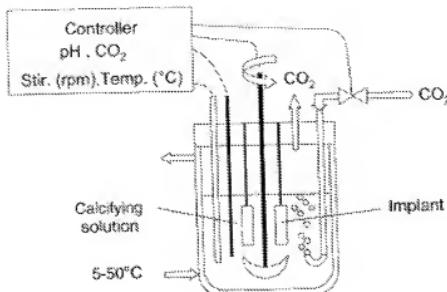


FIG. 1

Layrolle discusses alternative prior art techniques for achieving calcium phosphate coatings, such as plasma spraying, flame spraying, etc. Layrolle teaches that the prior art techniques are not desirable because anchoring the coating to the implant requires elevated temperatures. See paragraphs 0004 and 0005.

Layrolle then discusses the technique of soaking the implant in a highly concentrated calcifying solution, wherein calcium, phosphate, magnesium, etc., are dissolved into water by bubbling carbon dioxide gas. "During the natural release of carbon dioxide gas or its exchange with air, the pH of the calcifying solution is increased and the saturation is raised until the nucleation of carbonated calcium phosphate crystals on the surface of implantable devices. The said layer deposited and growth onto the medical implants. The process of bubbling/releasing CO₂ gas through or from calcifying solutions can be repeated until a sufficient thickness has been reached." See paragraph 0018.

Thus, Layrolle coats stents by depositing/growing the coating on the stent while the stent is immersed in a solution that includes the coating material(s).

The prior art can only be modified or combined to reject claims as *prima facie* obvious when there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)

A person of ordinary skill in the art would not have recognized a reasonable expectation of success in attempting to coat a stent with coating materials taught by Layrolle, but applied by a roller coating machine as taught by Pacetti. Therefore a person of ordinary skill in the art would not have been motivated to modify Pacetti/Shibata in view of Layrolle as asserted

by the Examiner, and a *prima facie* case of obviousness has not been presented.

Any assertion by the Examiner that the rejection is only proposing to incorporate the concept of a “fermentor” or “cultured cells” into the roller coating system amounts to a conclusory rejection motivated by impermissible hindsight. The Examiner has not articulated any reason why the particular concept(s) of a fermentor and/or cultured cells have been dissected, out of context, from Layrolle.

Applicants request that the Board reverse the rejection of claim 19.

Issue 5: Whether the Examiner erred in rejecting claim 39 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Pomper (US 2842092).

The rejections discussed under Issue 5 rely upon reasoning from the primary combination of Pacetti and Shibata, which is discussed under Issue 2. If the rejections over Pacetti and Shibata are reversed, the rejections discussed under Issue 5 should be reversed for at least the reasons discussed with respect to Issue 2.

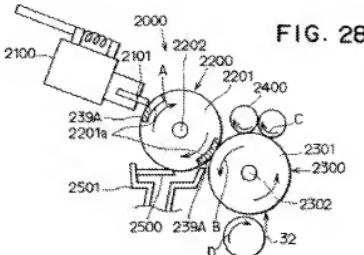
Further, a person of ordinary skill in the art would not have been motivated to make the first roller moveable to adjust a distance between the first and second rollers of the Pacetti/Shibata device proposed by the Examiner because the modification would not have any useful result. Further, there would not be a reasonable expectation of success that the modification would actually result in an ability to further meter the coating.

Claim 39 recites, “wherein a distance between the first roller and the second roller is adjustable to control the thickness of the coating material.”

The Examiner asserts the following at page 7 of the Non-Final Office Action:

It would have been obvious to one of ordinary skill in the art to provide at least one adjustable roller provided in the roller pair (first roller or second roller) in the indirect arrangement as defined by the combination above in order to control the distance between the two rollers so as to control the thickness of coating supplied on the stent.

This assertion is traversed. The combination of Pacetti and Shibata proposed by the Examiner would result in a device having a marking roller 2200 and a transfer roller 2300, as taught by Shibata. See e.g. Figure 28 from US 6111345 below.



The Examiner proposes to make one of the rollers 2200, 2300 a metering roller by providing adjustability in the distance between the rollers 2200, 2300; however, the modification is not necessary and would not present any useable benefit.

US 6111345 teaches that the coating material is supplied from the paste supplying portion 2101 to the recesses 2201a of the marking roller 2200. See US 6111345 at column 21, lines 23-29. Thus, the coating material in the Shibata device is already metered by the recesses 2201a of the marking roller 2200.

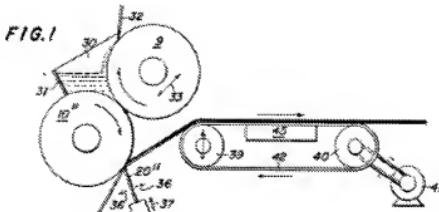
The transfer roller 2300 is made from an elastic material. The elasticity allows it to remove the coating material from the recesses 2201a of the marking roller 2200. The coating material is then transferred to the device being coated. See US 6111345 at column 21, lines 30-40.

The Examiner's proposal to provide distance adjustability between the marking roller 2200 and transfer roller 2300 would not achieve any useful result, and could further render the device unsuitable for performing a coating process.

Adjusting the distance between the rollers would not be expected to provide a reliable metering control over the coating because the transfer roller 2300 merely removes the coating from the recesses 2201a of the marking roller 2200. The transfer roller 2300 has no metering function. If the elastic surface of the transfer roller 2300 is able to contact the coating material positioned in the recesses 2201a of the marking roller 2200, the material will be removed from the recesses 2201a and transferred to the object being coated. If the elastic surface of the transfer roller 2300 is not able to contact the coating material positioned in the recesses 2201a, the material will not be removed from the recesses 2201a, and the device would not properly

transfer the coating.

In the Pomper device, the distance adjustability (see reference character 33 in Figure 1 below) provides for metering in conjunction with dams 30, 31 that create a reservoir, and gravity, which acts to pull the coating material through the metering gap. See e.g. Figure 1.



A person of ordinary skill in the art would recognize that providing distance adjustability between the marking roller 2200 and transfer roller 2300 taught by Shibata would not result in the metering function taught by Pomper because the distance between the marking roller 2200 and transfer roller 2300 does not control a flow of material from a reservoir that drains as a result of gravity. Therefore, a person of ordinary skill in the art would not have been motivated to provide distance adjustability between the Shibata rollers, as asserted by the Examiner.

Applicants request withdrawal of the rejection of claim 39.

Argument Conclusion

Based on at least the foregoing arguments, Applicants respectfully assert that the rejections presented by the Examiner fail to establish a *prima facie* case of obviousness against any of the pending claims. Accordingly, Applicants respectfully request that the Board reverse all of the rejections asserted by the Examiner.

Respectfully submitted,

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(viii) **Claims Appendix**

17. The system of claim 22, which further comprises a reservoir that continuously supplies the coating material source with coating material.
19. The system of claim 17, wherein the reservoir is a fermentor containing cells.
20. The system of claim 17, wherein the coating material is circulated between the reservoir and the coating material source.
21. The system of claim 22 wherein the surface of the second roller comprises a plurality of grooves.
22. A system for coating a stent having a tubular portion with an outer surface, wherein the system comprises:

a coating material source containing a coating material comprising a solvent and a biologically active material;

a first roller having a surface;

a doctor blade in proximity to the first roller surface positioned to remove excess coating material from the first roller surface; and

a second roller having a surface, wherein:

the first roller is situated relative to the coating material source so that the coating material in the coating material source is transferred to the first roller surface;

the first roller and second roller are situated relative to each other so that the first roller transfers the coating material transferred to the first roller surface to the second roller surface, and

the second roller is situated relative to the tubular portion so that the second roller transfers the coating material transferred to the second roller surface to the outer surface of the tubular portion.

23. The system of claim 22, wherein the surface of the second roller is rougher than the surface of the first roller.

24. The system of claim 22, wherein the surface of the first roller contacts the surface of the second roller and the surface of the second roller contacts the outer surface of the tubular portion.

25. The system of claim 22, further comprising a supplemental mechanism for removing excess coating material from the surface of the first roller.

26. The system of claim 25, wherein the supplemental mechanism is at least one of a metering roller or an air knife.

27. The system of claim 22, further comprising an energy source for converting the coating material applied to the outer surface of the tubular portion into a coating.

28. The system of claim 27, wherein the energy source is a heater.

29. The system of claim 27, wherein the energy source is an ultraviolet source.

36. The system of claim 22, wherein the biologically active material comprises a genetic material.

37. The system of claim 22, wherein the biologically active material comprises an antibiotic or an antiproliferative agent.

38. The system of claim 22, wherein said first roller surface comprises an outer surface.

39. The system of claim 22, wherein a distance between the first roller and the second roller is adjustable to control the thickness of the coating material.

(ix) Evidence Appendix

None

(x) Related Proceedings Appendix

None